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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,720	08/25/2003	Christine Markert-Hahn	810102.401	3616

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EXAMINER	
TUNG, JOYCE	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/647,720	MARKERT-HAHN ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The applicant's response filed 9/13/2006 to the Office action has been entered. Claims 1-11 are pending.

1. The rejection of claims 1-2 and 4-11 under 35 U.S.C. 112, second paragraph is withdrawn because of the amendment.

2. Claims 1-11 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10540406. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 1-11 and claims 1-7 of copending Application No. 10540406, both are drawn to a method for the conversion of a cytosine base in a nucleic acid to an uracil base. The differences are that claims 1-7 of copending Application No. 10/540,406 require more specific temperature, the concentration of bisulfite in the solution and the pH value for deaminating a nucleic acid, while the instant claims 1-11 do not have these specific limitations except that the instant claims 1-11 require a solid phase which binds to a nucleic acid. Claims 1-7 of copending Application No. 10540406 also require a solid phase, which binds to a nucleic acid (See pg. 7, lines 5-12 of the specification). Thus the instant claims and claims 1-7 of copending Application No. 10540406 are related as genus-species. The double patenting rejection is applicable.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The response does not include a terminal disclaimer. Thus, the rejection is maintained.

3. Claim 1 remains rejected under 35 U.S.C. 102(b) as being anticipated by Olek et al. (Nucleic Acid Research, 1996, Vol. 24924, pg. 5064-5066).

Olek et al. disclose sequencing of bisulphate modified genomic DNA, which involves the method steps, recited in claim 1 for the conversion of cytosine to uracil (See pg. 5064, column 2, third paragraph, pg.5065, column 1, paragraphs 2 and 3). Thus, the teachings of Olek et al. anticipate the limitations of claim 1 that are binding the nucleic acid to a solid phase, incubating the solid phase bound nucleic acid in the presence of sulfite ions, incubating the deaminated nucleic acid under alkaline conditions.

The response argues that Olek et al. fail to teach the step of "binding the nucleic acid to a solid phase" and Olek et al. disclose utilizing low melting point agarose beads into which denature DNAs or cells of DNA to be analyzed are embedded. However, as disclosed by Olek et al. the isolated DNAs digested were mixed with 2 vol of 2% low melting point agarose dissolved in water and then the mixture of agarose/DNA was directly pipetted into chilled mineral oil to form agarose beads (See pg. 5064, column 2,last paragraph to pg. 5065, column 1, first paragraph). It was also well known in the art at the time of the instant invention, agarose is a material used to make gel with pores. The specification indicates that nucleic acid is directly bound without any compound mediating the binding to the surface whereby binding to the surface also takes into account that the solid phase may contain pores and that the nucleic acid may be bound to surfaces in pores of the solid phase (See pg. 4, lines 4-9 of the specification). Nevertheless, there is no limitation regarding how the binding to take place. Moreover the "deaminated solid phase" recited in claim 1 is produced by the deaminated nucleic acid bound to

the solid phase (See claim 1). Thus, based upon the analysis above, the teachings of Olek et al. are inherent that the nucleic acid is bound to a solid phase. Therefore, the rejection is maintained.

4. Claims 2-3 remain rejected under 35 U.S.C. 102(b) as being anticipated by Herman et al. (5,786146, issued July 28, 1998).

Herman et al. disclose a methylation specific PCR (See the Abstract). The method involves the step of conversion cytosine to uracil as recited in claims 2-3 (See column11, lines 16-28). Bisulfite modification includes incubating the nucleic acid in the presence of sulfite ions, binding the deaminated nucleic acid to a solid phase, incubating the deaminated nucleic acid under alkaline conditions, eluting the deaminated nucleic acid from the solid phase and incubating the deaminated nucleic acid under alkaline conditions. Thus the teachings of Herman et al. anticipate the limitation of the claims.

The rejection is made over the teachings of Herman et al. (5,786146, issued July 28, 1998). The argument of the response is based upon the teachings of Herman et al. (Proc. Natl. Acad. Sci. USA, 93: 9821-26, 1996).

Nevertheless, the response argues that claims 2 and 3 require that nucleic acid be bound to a solid support not only for purification, but also for subsequent incubation and other steps, while Herman et al. (5,786146, issued July 28, 1998) may have isolated DNA using a solid support, this does not teach the prolonged attachment recited in claims 2 and 3. However, regardless of the intended use (purification), the teachings of Herman et al. anticipate the limitations of the claims (See column11, lines 16-28). Therefore, the rejection is maintained.

5. Claims 4-11 are rejected under 35 U.S.C. 103(a) as being respectively unpatentable over Olek et al. (Nucleic Acid Research, 1996, Vol. 24924, pg. 5064-5066) or Herman et al.

(5,786146, issued July 28, 1998) as applied to claims 1-3 above, and further in view of Weindel et al. (WO 01/37291, issued May 21, 2001).

The teachings of Olek et al. and Herman et al. respectively set forth in sections 9 and 10 above. Olek et al. and Herman et al. do not disclose the solid phase comprises silica or glass or glass membrane or magnetic glass particle, the magnetic particle has diameter between 0.5 and 5um, and the magnetic glass particle is manufactured by the sol-gel method.

Weindel et al. disclose the magnetic glass particle, which can be used in nucleic acid purification (See the abstract). The magnetic glass particle is a solid dispersion of small magnetic core in glass (See pg. 4, lines 9-11). The diameter of the particle is between 5 and 500nm (See pg. 4, lines 21-23 and pg. 5, lines 13-23). The magnetic glass particle is used in nucleic acid purification from a sample containing cells. The advantage of this is its potential simplicity and high sensitivity (See pg. 17, lines 1-7). Weindel et al. also disclose the method of making the magnetic glass particle by the sol-gel method and spray-drying as recited in instant claim 11 (See pg. 9, lines 13-37, pg. 21 and fig. 1). The magnetic glass particle is also used in nucleic acid amplification and hybridization assay (See pg.1).

One of ordinary skill in the art would have been motivated to apply the magnetic glass particle of Weindel et al. in the method of Olek et al. or Herman et al. as a solid support for conversing cytosine bases in nucleic acid to uracil because of the advantage of using the magnetic glass particle (See pg. 17, lines 1-17). It would have been prima facie obvious to apply the magnetic glass particle for the conversion of cytosine bases to uracil bases in a nucleic acid.

The response argues that Weindel et al. do not cure the deficiencies of Olek and Herman. However, as set forth above, Weindel et al. disclose the magnetic glass particle, which can be

used in nucleic acid purification (See the abstract). The magnetic glass particle is a solid dispersion of small magnetic core in glass (See pg. 4, lines 9-11). The advantage of this is its potential simplicity and high sensitivity (See pg. 17, lines 1-7). The magnetic glass particle is also used in nucleic acid amplification and hybridization assay (See pg.1). Thus, it would have been prima facie obvious to apply the magnetic glass particle for the conversion of cytosine bases to uracil bases in a nucleic acid. Thus the rejection is maintained.

NEW GROUND OF REJECTION NECESSITATED BY THE AMENDMENT

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-11 are vague and indefinite because of the ~~definition of the~~ phrase "deaminated solid phase". It is unclear how the deaminated solid phase is made. Clarification is required.

Summary

7. No claims are allowable.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung
November 28, 2006

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

11/29/06